

REMARKS

Claims 1-24 were presented in the application as filed. Group V was elected in a Response filed January 11, 2007 and claims 25-34 were added in the same Response. Claims 15-17 and 25-34 are amended. Claims 15-17 and 25-34 are pending. Reconsideration of the application and allowance of all claims pending herein are respectfully requested in view of the remarks below.

CLAIM OBJECTIONS

Claims 15-17 and 25-34 have been amended to comply with the Examiner's objections. Reconsideration of the objections is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 16 and 17 have been amended to comply with the Examiner's rejections. Antecedent basis had been provided for the polymer limitation in the foregoing claims by amending the term "polymer" to "copolymer". The amendments correct a typographical error in the originally filed claims. No new matter has been added. Reconsideration of the rejections is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103

The Office action states that claims 15-17 and 31-32 are rejected under 35 U.S.C. §103(a) as being unpatentable over Laboratoire de Recherches Physiques (LRP), (GB 1,098,006) in view of Blaser *et al.* (U.S. 2,764,576). Claim 15 is independent.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations [see, MPEP 2143].

As to claim 15, LRP teaches pharmaceutical compositions having a sustained release of a pharmaceutically active ingredient. The composition typically comprises a tablet or a pellet

that is coated with two layers. The first layer is impermeable to gastric fluids and the pharmaceutically active ingredient, and the second layer (referred to as a dialyzing membrane) is permeable to gastric fluids and the pharmaceutically active ingredient. The rate of release of the pharmaceutically active ingredient may be controlled by varying the configuration of the two layers relative to the tablet; see page 1, lines 12-28. The dialyzing membrane may be formed from a variety of film-forming materials, one of which is a sulfonated polystyrene polymer; see page 1, lines 29-42.

The Examiner alleges that the sulfonated polystyrene polymer taught in LRP is the sulfonated styrene copolymer of Applicants' claim 15. The Applicants respectfully assert that the foregoing interpretation is incorrect. The sulfonated polystyrene polymer taught in LRP is a homopolymer. It contains only one type of repeating unit, *i.e.*, a unit resulting from a styrene monomer. The sulfonated styrene of the Applicants' invention is a copolymer. It contains at least two different repeating units in the polymer chain. One unit derived from the styrene monomer and the at least second unit derived from a monomer other than styrene. Nowhere in LRP is taught a single example of a pharmaceutical composition comprising a copolymer, let alone a sulfonated polystyrene copolymer. LRP only discloses a sulfonated polystyrene homopolymer as a tablet coating in the pharmaceutical compositions disclosed therein.

As to claim 15, Blaser *et al.* simply teaches the preparation of water-soluble sulfonated styrene polymers, specifically, a sulfonated styrene polymer (Ex. 1, 2, and 4), a sulfonated styrene-acrylonitrile copolymer (Ex. 5), and a salt of a sulfonated styrene polymer (Ex. 3). Blaser *et al.* does not teach or suggest a method for controlling biological organisms on a porous surface as recited in Applicants' claim 15.

The Examiner alleges that it would have been obvious to one of ordinary skill in the art to form a coating comprising a salt of a sulfonated styrene copolymer on a porous surface because of motivation provided by the teachings of LRP and in light of the process of converting a sulfonated polystyrene acid to a base taught by Blaser *et al.* The Applicants' respectfully assert that a *prima facie* case of obviousness has not been established.

First, there is no suggestion or motivation, in LRP or Blaser *et al.*, or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings. The language of the preamble of Applicants' claim 15, a method for controlling biological organisms on a porous surface, limits the invention as a whole and gives meaning to claim 15 in order to properly define the invention. LRP only discloses a pharmaceutical composition for sustained release of a pharmaceutically active ingredient.

Blaser *et al.* only teaches the preparation of water-soluble sulfonated styrene polymers for possible use in adhesives, as thickeners, and as stabilizers in emulsions. Neither LRP nor Blaser *et al.* teach or suggest, independently or in combination, a method for controlling biological organisms on a porous surface as recited in Applicants' claim 15. Therefore, one having ordinary skill in the art would not be motivated to modify or to combine the foregoing references to arrive at Applicants' invention as recited in claim 15.

Second, LRP and Blaser *et al.*, independently or in combination, do not teach or suggest all the claim limitations of Applicants' claim 15. Applicants' method for controlling biological organisms on a porous surface comprises forming a coating comprising a salt of a sulfonated styrene copolymer on a porous surface. LRP does not teach or suggest a sulfonated styrene copolymer coating for use on a porous surface; see discussion *supra*. Blaser *et al.* does not remedy the deficiency of LRP.

In light of the above, Applicants respectfully assert that a *prima facie* case of obviousness has not been established. LRP and Blaser *et al.* do not provide a suggestion or motivation to modify the references or to combine the reference teachings, and do not teach or suggest, independently or in combination, all the claim limitations of Applicants' claim 15. Therefore, LRP and Blaser *et al.* do not render Applicants' claim 15 obvious. Reconsideration of claim 15 under 35 U.S.C. § 103(a) is requested. Claims 16 and 17, which depend from claim 15 and add further limitations to an allowable claim, are believed allowable for the same reasons.

As to claims 31 and 32, LRP teaches a pharmaceutical composition comprising a sulfonated polystyrene homopolymer as a tablet coating in a pharmaceutical composition; see discussion *supra*. LRP also teaches the use of a pharmaceutically active ingredient, oxytetracycline hydrochloride, in the pharmaceutical compositions disclosed therein. The oxytetracycline hydrochloride is incorporated into the tablet or the pellet of the pharmaceutical composition; see page 2, lines 17-62. Nowhere in LRP is it taught or suggested that the oxytetracycline hydrochloride is incorporated into the sulfonated polystyrene homopolymer coating, let alone a sulfonated polystyrene copolymer coating as recited in Applicants' claims 31 and 32. Blaser *et al.* does not remedy the deficiencies of LRP.

In light of the above, Applicants respectfully assert that a *prima facie* case of obviousness has not been established. LRP and Blaser *et al.*, independently or in combination, do not teach or suggest, all the claim limitations of Applicants' claims 31 and 32, and therefore, LRP and Blaser *et al.* do not render Applicants' claims 31 and 32 obvious. Reconsideration of claims 31 and 32 under 35 U.S.C. § 103(a) is requested.

The Office action states that claims 25, 26, 33, and 34 are rejected under 35 U.S.C. §103(a) as being unpatentable over Laboratoire de Recherches Physiques (LRP), (GB 1,098,006) in view of Blaser *et al.* (U.S. 2,764,576) as applied to claims 15-17 and 31-32 above, in further view of McIntosh (US 4,996,052).

As to claims 25, 26, 33, and 34, LRP only discloses a sulfonated polystyrene homopolymer as a tablet coating in the pharmaceutical compositions described therein. LRP does not teach a single example of a pharmaceutical composition comprising a sulfonated polystyrene copolymer; see discussion *infra* regarding claims 15, 31, and 32. Blaser *et al.* teaches the preparation of water-soluble sulfonated styrene polymers, specifically, the conversion of a sulfonated styrene polymer acid to a salt. Blaser *et al.* does not teach or suggest a method for controlling biological organisms on a porous surface; see discussion *supra* regarding claims 15, 31, and 32. McIntosh teaches a microbiocidal composition comprising a phosphate derivative as an active agent and a method for preparing such. McIntosh generically discloses the microbiocidal composition additionally comprising a polymer and copolymer, and specifically discloses one copolymer, *i.e.*, vinyl chloride-vinylidene chloride copolymer. McIntosh does not teach or suggest a method for controlling biological organisms comprising a coating comprising a sulfonated styrene copolymer. The Applicants' respectfully assert that a *prima facie* case of obviousness has not been established.

First, there is no suggestion or motivation, in LRP or Blaser *et al.*, or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings; see discussion *supra* regarding claim claims 15, 31, and 32. The sulfonate of the sulfonated styrene copolymer coating is important to controlling biological organisms on the porous surface. The polyanionic nature of the sulfonated styrene copolymer provides a biocompatible and stabilizing environment for providing drugs and biomolecules such as proteins and peptides, and the sulfonate groups themselves are advantageous to healing of chronic wounds and the like. McIntosh teaches a microbiocidal composition comprising a phosphate derivative as the sole active medicinal agent. McIntosh does not teach or suggest any other agents for use in the compositions therein, let alone other medicinal agents used in combination with the sulfonated styrene copolymer coating of Applicants' invention and the limitations of claims 25, 26, 33, and 34.

Neither LRP, Blaser *et al.*, nor McIntosh teach or suggest, independently or in combination, a method for controlling biological organisms on a porous surface by forming a coating comprising a sulfonated polystyrene copolymer as recited in Applicants' claims 25, 26,

33, and 34. Therefore, one having ordinary skill in the art would not be motivated to modify or to combine the foregoing references to arrive at Applicants' claimed invention.

Second, neither LRP, Blaser *et al.*, nor McIntosh, independently or in combination, teach or suggest all the claim limitations of Applicants' claims 25, 26, 33, and 34. Applicants' method for controlling biological organisms on a porous surface comprises forming a coating comprising a salt of a sulfonated styrene copolymer on the porous surface. LRP does not teach or suggest a sulfonated styrene copolymer coating for use on a porous surface; see discussion *supra*. Blaser *et al.* and McIntosh, independently or in combination, do not remedy the deficiency of LRP.

In light of the above, Applicants respectfully assert that a *prima facie* case of obviousness has not been established. LRP, Blaser *et al.*, and McIntosh do not provide a suggestion or motivation to modify the references or to combine the reference teachings, and do not teach or suggest, independently or in combination, all the claim limitations of Applicants' claims 25, 26, 33, and 34. Therefore, LRP, Blaser *et al.*, and McIntosh do not render foregoing claims obvious. Reconsideration of claims 25, 26, 33, and 34 under 35 U.S.C. § 103(a) is requested.

The Office action states that claims 27 and 28 are rejected under 35 U.S.C. §103(a) as being unpatentable over Laboratoire de Recherches Physiques (LRP), (GB 1,098,006) in view of Blaser *et al.* (U.S. 2,764,576) as applied to claims 15-17 and 31-32 above, in further view of Richmond (US 3,081,291).

As to claims 27 and 28, the description of LRP and Blaser *et al.*, and their deficiencies have been thoroughly discussed *supra*. Richmond teaches the polymerization of gaseous ethylene using a solid polymer, chromium salt catalyst containing methacrylic acid. Richmond teaches various embodiments of the solid polymer, chromium salt catalyst. In one embodiment the catalyst may contain carboxy substituents and in another embodiment the catalyst may contain sulfo substituents. Examples 5(A) and 5(B) describe the preparation of a solid copolymer, chromium salt catalyst, *i.e.*, the copolymer being 50/50 styrene and methacrylic acid, and containing a heavy metal. The foregoing solid polymer, chromium salt catalyst and others are subsequently used to catalyze the polymerization of gaseous ethylene monomers to a solid polyethylene polymer.

Nowhere in Richmond is taught or suggested the polymerization of ethylene with another monomer to form a polyethylene copolymer, let alone a sulfonated styrene copolymer. As demonstrated by each polymerization example in the specification, the specific invention is the

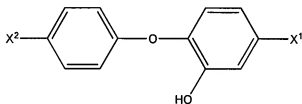
polymerization of gaseous ethylene monomers to form a solid polyethylene polymer. The only product isolated and characterized is solid polyethylene, *i.e.*, a homopolymer. One having ordinary skill in the art of polymer chemistry will recognize and understand that incorporation of a catalyst into a polymer resulting from a polymerization process does not necessarily make the catalyst a comonomer and subsequently the polymer a copolymer. In the examples taught by Richmond, the solid polymer, chromium salt catalyst is incorporated into the final polyethylene/polymer matrix but the catalyst does not react with the gaseous ethylene monomers so as to form repeating units within the final polyethylene/polymer chain. Richmond does not teach or suggest the preparation of a sulfonated styrene copolymer, or a method of use for controlling biological organisms on a porous surface.

The Applicants' respectfully assert that a *prima facie* case of obviousness has not been established. First, neither LRP, Blaser *et al.*, nor Richmond teach or suggest, independently or in combination, a method for controlling biological organisms on a porous surface by forming a coating comprising a sulfonated polystyrene copolymer as recited in Applicants' claims 27 and 28 as set forth in the arguments *supra*. Therefore, one having ordinary skill in the art would not be motivated to modify or to combine the foregoing references to arrive at Applicants' claimed invention. Second, neither LRP, Blaser *et al.*, nor Richmond, independently or in combination, teach or suggest all the claim limitations of Applicants' claims 27 and 28. Applicants' method for controlling biological organisms on a porous surface comprises forming a coating comprising a salt of a sulfonated styrene copolymer on a porous surface. LRP does not teach or suggest a sulfonated styrene copolymer coating for use on a porous surface; see discussion *supra*. Blaser *et al.* and Richmond, independently or in combination, do not remedy the deficiency of LRP.

In light of the above, Applicants respectfully assert that a *prima facie* case of obviousness has not been established. LRP, Blaser *et al.*, and Richmond do not provide a suggestion or motivation to modify the references or to combine the reference teachings, and do not teach or suggest, independently or in combination, all the claim limitations of Applicants' claims 27 and 28. Therefore, LRP, Blaser *et al.*, and Richmond do not render claims 27 and 28 obvious. Reconsideration of claims 27 and 28 under 35 U.S.C. § 103(a) is requested.

The Office action states that claims 27-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Laboratoire de Recherches Physiques (LRP), (GB 1,098,006) in view of Blaser *et al.* (U.S. 2,764,576) as applied to claims 15-17 and 31-32 above, in further view of Svenningsen *et al.* (US 6,664,309).

As to claims 27-30, the Applicants' respectfully assert that a *prima facie* case of obviousness has not been established. First, LRP and Blaser *et al.* combined do not suggest or provide motivation for a coating formed from a sulfonated styrene copolymer and the incorporation of antibiotics into the sulfonated styrene copolymer coating; see all discussions *supra*. Svenningsen *et al.* teaches an anti-microbial hot melt adhesive. The anti-microbial agents, referred to as bacteriostats, include benzoates, phenols, aldehydes, halogen containing compounds, nitrogen compounds, and metal containing compounds such as mercurials, zinc compounds, and tin compounds. The preferred bacteriostat is a compound of the formula:



wherein X¹ is a member selected from the group consisting of chlorine and bromine, X² is a member selected from the group consisting of chlorine and bromine, and X³ is a member selected from the group consisting of hydrogen and chlorine. Svenningsen *et al.* suffers the same deficiencies as McIntosh, *i.e.*, does not teach a sulfonated styrene copolymer coating and the advantages afforded by the use of a sulfonate.

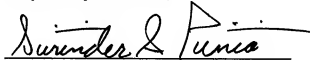
Svenningsen *et al.* does not remedy the suggestion and motivation lacking in the combination of LRP and Blaser *et al.* Therefore, one having ordinary skill in the art would not be motivated to modify or to combine the foregoing references to arrive at Applicants' invention as recited in claims 27-30. Second, LRP or Blaser *et al.*, independently or in combination, do not teach or suggest all the claim limitations of Applicants' claims 27-30. Applicants' method for controlling biological organisms on a porous surface comprises forming a coating comprising a salt of a sulfonated styrene copolymer on the porous surface. LRP does not teach or suggest a sulfonated styrene copolymer coating for use on a porous surface; see discussion *supra*. Svenningsen *et al.* does not remedy the deficiency of LRP and Blaser *et al.*

In light of the above, Applicants respectfully assert that a *prima facie* case of obviousness has not been established. LRP, Blaser *et al.*, and Svenningsen *et al.* do not provide a suggestion or motivation to modify the references or to combine the reference teachings, and do not teach or suggest, independently or in combination, all the claim limitations of Applicants' claims 27-30. Therefore, LRP, Blaser *et al.*, and Svenningsen *et al.* do not render claims 27-30 obvious. Reconsideration of claims 27-30 under 35 U.S.C. § 103(a) is requested.

There being no other outstanding issues, it is believed that the application is in condition for allowance, and such action is respectfully requested.

If a telephone conference would be of assistance in advancing the prosecution of the subject application, Applicants' undersigned agent invites the Examiner to telephone him at the number provided.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'Surinder S. Punia', written over a horizontal line.

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